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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/621,565	07/21/2000	Miri Seiberg	JBP0510	4999
7590 09/27/2005				
Audley A Ciamporcero Jr Esq Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003			EXAMINER FUBARA, BLESSING M	
			ART UNIT 1618	PAPER NUMBER

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/621,565	Applicant(s) SEIBERG ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 68-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 68-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/23/05 & 4/21/05</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Examiner acknowledges receipt of IDS filed 3/23/05 and 4/21/05; request for continued examination, non-complaint amendment and remarks filed 05/09/05; and compliant amendment and remarks filed 06/30/2005. Claims 1-22 and new claims 68-70 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 05/09/05 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 6, 7, 9, 16 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Costanzo (US 6,323,219).

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Costanzo discloses method and composition for “bringing about skin pigmentation and/or for causing skin depigmentation;” the methods and composition of Costanzo can be used as depigmenting compositions, darkening compositions and as compositions for preventing and/or treating immunomediated inflammatory diseases such as asthma and allergic rhinitis (abstract). The composition of Costanzo contains serine protease inhibitors that may be obtained from extracts of Solanaceae, Gramineae, Cucurbitaceae and Leguminosae (column 8, lines 52-67); soybean milk also contains serine protease (column 9, lines 47-53; column 28, lines 50-67).

Costanzo specifically discloses topically applying to mammalian skin pharmaceutical or cosmetic composition in an amount effective to effect changes in pigmentation (column 10, lines 13-17) and soybean milk or other formulations derived directly from legumes is applied to the mammalian skin (column 9, lines 47-52). Costanzo lists gray hair as one of the skin disorders treatable with the composition (column 30, lines 14-27).

The instant method involves topical application to the skin a topically active composition that comprises one or more compounds derived from one or more of the botanical families. Since the instant method topically applies a composition and Costanzo topically applies to the skin a composition that reads of the instant composition, it would be inherent that the composition of the prior art affects the skin the same way as the instant composition affects the skin. The effect of the composition is inherent. Thus, although Costanzo does not specifically disclose that the composition has an effect on hair growth, since the instant claim 1 and Costanzo apply the same composition to the skin, the effect on the skin from both compositions would be the same.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4, 5, 8, 10-14, 16-18, 20-22 and 68-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Costanzo (US 6,323,219) in view of Matsuura et al. (US 6,139,899).

The teaching of Costanzo is discussed above and Costanzo discloses the method of the instant claims, that is, topically applying a composition comprising extracts from the plants Solanaceae, Gramineae, Cucurbitaceae and Leguminosae as discussed above. Regarding claims 4 and 5, there is no showing demonstrating that the amount of the inhibitor provides unusual results. Generally, reciting amounts of serine protease inhibitor will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount is critical. "W[here] the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding claims 11-14, 16-18 and 20-22, since the composition of the prior art is applied to the skin, the composition would inherently exhibit the properties of the composition on the skin. Regarding new claims 68-70, it is respectfully noted that the instant method involves application of the composition to the skin to effect inhibition of hair growth, reduction

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of hair follicle and hair shaft and reduction of hair pigmentation, the prior art applies a composition containing serine protease inhibitor and it would be expected that composition similar to the composition of the instant claims would have the same effect on the skin or hair when topically applied to the skin. Thus, in the alternate, it would be obvious for the same/similar composition to have the same/similar effect on the skin and on the hair.

Regarding claims 8-10, Costanzo does not disclose that the composition comprising the plant extracts contains isoflavones. However, the composition of the prior art Costanzo contains soybean milk extract. But it is known in the prior art, for example, Matsuura, that soybean milk contains isoflavones. Matsuura discloses the presence of isoflavones in soybean milk (abstract; see the whole document). Thus, Matsuura is relied upon for a teaching that soybean milk contains isoflavones. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the composition of Costanzo containing extract of soy bean milk to apply to the skin in order to effect changes in mammalian hair appearance/skin pigmentation/skin depigmentation. One having ordinary skill in the art would have been motivated to apply the composition of Costanzo to the skin with the expectation that the composition containing the extract of soybean milk contains isoflavones that occur naturally in the soybean milk as disclosed by Matsuura and expect the composition to produce changes in the mammalian hair/skin appearance.

Response to Arguments

7. Applicants state that Costanzo does not disclose applying topical composition to skin or hair to change its appearance, "or in such a way as to effect a delay in hair growth or facilitate removal of hair, ... or improving hair style or hair management." Applicants further argue that

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the JP reference cited in the final rejection teaches away from the invention by disclosing specific isoflavone so that the effect is that the JP reference discloses stimulation of hair growth.

8. Applicants' arguments filed 05/09/05 have been fully considered but they are not persuasive.

Regarding the JP reference and the specific isoflavone disclosed, it is noted that the claims are directed to generic isoflavone, no specific isoflavone is claimed and as such the generic isoflavone reads on any isoflavone. Secondly, the JP reference was relied upon for a teaching that soybean milk contains isoflavones. Thirdly, how would the isoflavone of the instant claims reduce hair growth and the isoflavone of the prior art stimulate hair growth? However, the new rejection relies on another art, which discloses that soybean milk contains isoflavones. Similarly, in this case, no specific isoflavone is claimed by the instant claims.

9. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

A handwritten signature in black ink, appearing to read "Bfubara", is written over the printed name "Blessing Fubara".